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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------------|------------------|
| 10/553,285 | 10/14/2005 | Gema Tarrason | MERCK-3081 | 8617 |
| 23599 7590 01/11/2007 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201 | | | EXAMINER RUSSEL, JEFFREY E | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1654 | |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
| 3 MONTHS | | 01/11/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/553,285 | TARRASON ET AL. | |
| | Examiner | Art Unit | |
| | Jeffrey E. Russel | 1654 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 October 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20051014</u> | 6) <input type="checkbox"/> Other: _____ |

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1. The informal drawings are not of sufficient quality to permit examination. Accordingly, replacement drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to this Office action. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action.

Failure to timely submit replacement drawing sheets will result in ABANDONMENT of the application.

2. The abstract of the disclosure is objected to because of the presence of legal phraseology "said". Also, the use of complete sentences is preferred. Correction is required. See MPEP § 608.01(b).

3. The disclosure is objected to because of the following informalities: At page 5, line 22, "highest" is misspelled. At page 6, line 16, "Cell" should be changed to "Cells". At page 6, line 20, "phosphatidyl" is misspelled. At page 14, line 9, "alignment" is misspelled. At page 20, line 6, "Stoichiometry" is misspelled. Appropriate correction is required.

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 5-7 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A "Use" is not a statutory class of invention.

5. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The use of the trademark "Taxol" in claims 1, 8, and 9 is indefinite. Because a

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trademark identifies a source of goods rather than the goods themselves, it is not clear what function "Taxol" is intended to serve in the instant claims. It is suggested that "Taxol" be replaced with the generic terminology "paclitaxel". See MPEP 2173.05(u). Claims 2 and 3 are indefinite because they state that R^2 is OR'; however, independent claim 1 does not permit R^2 to be OR'. Claims 2 and 3 are indefinite because they recite that "OR' is in para-position". It is not clear if this limitation refers to the group R^2 which may be OR' (although see the above rejection concerning this limitation), or if this limitation refers to the groups R^1 and/or R^4 which the independent claim positively states can be OR'. It is not clear what constitutes a "Use" as is recited in claims 5-7. It is not clear if Applicants intend to claim, e.g., a method of use, or a product with an intended use limitation. To the extent that the former is intended, the claims are indefinite because they are drawn to a method of use, but no positive process steps are recited. Claim 8 is indefinite because it is incomplete. The actual formula I is not included in the claim. Note that where possible, claims are to be complete in and of themselves. See MPEP 2173.05(s).

6. Claims 1-7 and 9 are objected to because of the following informalities: At claim 1, lines 6, 7, 8, and 10, the conjunction "or" should be inserted before the last member of each Markush group. Claims 1, 7, and 9 do not end with periods. At claim 9, line 2, "on a patient" should be inserted after "performing" (first occurrence) so as to provide antecedent basis for "the patient" at line 2 of the claim. At claim 9, line 4, "said" should be deleted in order to avoid issues of antecedent basis. Appropriate correction is required.

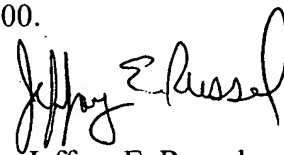
7. Claims 1-4, 8, and 9 are novel and unobvious over the prior art of record or any combination thereof. The prior art of record does not provide any motivation to combine compounds of Formula I with paclitaxel.

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8. The references crossed off of the Information Disclosure Statement filed October 14, 2005 were cited with incorrect publication numbers. The examiner has cited the references in the attached Notice of References Cited, Form PTO-892.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

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JRussel

January 4, 2007